## REMARKS

Claims 1-6 are pending in the present application and are rejected. Claims 1-6 are herein amended.

**Applicants' Response to Claim Rejections under 35 U.S.C. §103**

**Claims 1-6 were rejected under 35 U.S.C. §103(a) as being unpatentable over Kilpela et al. (U.S. Patent No. 6,364,885) in view of Hench et al. (WO 02/079108).**

It is the position of the Office Action that Kilpela discloses the embodiments as claimed, with the exception of teaching that the device is configured for cutting bone, and that the wire is a cutting wire. The Office Action relies on Hench to provide this teaching.

Kilpela is directed at a cable tensioning device used for strengthening bones. The tensioning device is illustrated in part in Figures 1 and 2. The device includes a gripping member 1, a handle 4 and a cam body 11. The gripping member 1 attaches to a bit 32. One end of a cerclage cable 46 is connected to a crimp 36 which slides into the bit 32. The cerclage cable 46 is formed into a loop 50 around a bone, and then the second end of the cerclage cable 46 is fed through the crimp 36 again, and then is fed through the cable tensioning device, such that the second end of the cerclage cable 46 protrudes from the cam body 11 (and can be held by cam lock 12). Using the tensioning device, the loop 50 is tightened until it reaches the appropriate tightness. At this point, the cable loop 50 is locked in place. See column 4, lines 51-58. In Kilpela, the cable tensioning device is used to hold together pieces of a broken bone.

In response, Applicants respectfully submit that Kilpela as modified by Hench does not disclose or suggest the embodiments as claimed. The Office Action appears to interpret Kilpela such that the cable 46 is three different wires. However, Applicants respectfully submit that this is improper. Claim 1 recites three distinct wires, and recites what is attached to each end of these three wires. This structure is summarized below:

| | **First end** | **Second end** |
|---|---|---|
| Cutting wire W1 | Attached to fastener 4 | Fixed to fixture 35 |
| First supporting wire W2 | Connected to first longitudinal end of cylindrical main portion 2 (nut 29) | Attached to fastener 4 |
| Second supporting wire W3 | Connected to second longitudinal end of cylindrical main portion 2 (fixture 6A) | Attached to fastener 4 |

The Office Action regards the cable 46 as a first supporting wire, regards the "opposing end of 46" as a second supporting wire, and regards the "loop 50" as the cutting wire. However, these are merely different portions of the same cable 46 of Kilpela. As explained above, the first end of the cable 46 is attached to the crimp 36. The second end of the cable 46 is fed through the crimp again, then is fed through the cable tensioning device, and protrudes from the cable tensioning device. The cable of Kilpela can only have two ends. As such, it is improper to interpret a single, continuous cable as three distinct cables, each having a first end and a second end. Therefore, Applicants respectfully submit that the combination of cited art does not disclose or suggest the embodiment of claim 1, and all claims dependent thereon. Applicants also submit that since Kilpela does not disclose or suggest a device having three wires, each having two ends,

it cannot disclose the further structure recited in claims 2-6. Additionally, Applicants note that claims 1-6 are herein amended in order to improve clarity and form.

Additionally, as to the combination of references, Applicants respectfully submit that one having ordinary skill in the art would have no reason to combine Kilpela and Hench. Kilpela is directed at an orthopedic cable "used to strengthen and repair broken bones." Column 1, lines 13-14. On the other hand, Hench is directed at cutting bioactive glass, and has little relation to bone. The Office Action cites to page 2, lines 5-10, page 2, lines 16-24 and page 3, lines 25-30. Despite the Office Action's allegation, none of these passages relate to cutting bone. As such, Applicants respectfully submit that one having ordinary skill in the art would not have a reason to combine a device relating to bone and a device relating to bioactive glass. Moreover, Applicants respectfully submit that Kilpela is directed at a device for holding something together (broken bones), while Hench is directed at a device for cutting something apart (bioactive glass). There is no reason why one having ordinary skill in the art would combine a holding-together device with a cutting-apart device.

Additionally, Applicants now provide additional comments regarding how the claimed bone cutter operates, and the difference in operation over a conventional bone cutter. The claims relate to a bone cutter for cutting a bone by wrapping a wire around the bone and pulling said wire. As described in the paragraph [0046] in reference with Fig. 6 and Table 1 of the present application, using a bone cutter as claimed, a bone having a dual structure, which includes a stiff external surface and a soft inner part, was clearly cut as expected. It is impossible to cut clearly a bone having a dual structure, which includes a stiff external surface and a soft inner part, by

merely wrapping a wire around such the bone and pulling the wire. In such a case, the stiff external surface can be cut by merely wrapping a wire around such the bone and pulling the wire. However, the soft inner part of the bone cannot be cut entirely and clearly, and therefore, the bone cannot be cut in two portions.

In the conventional art, as shown in Fig. F-2 (below), there is a non-cut portion P in the soft inner part Ix of the bone Bx.

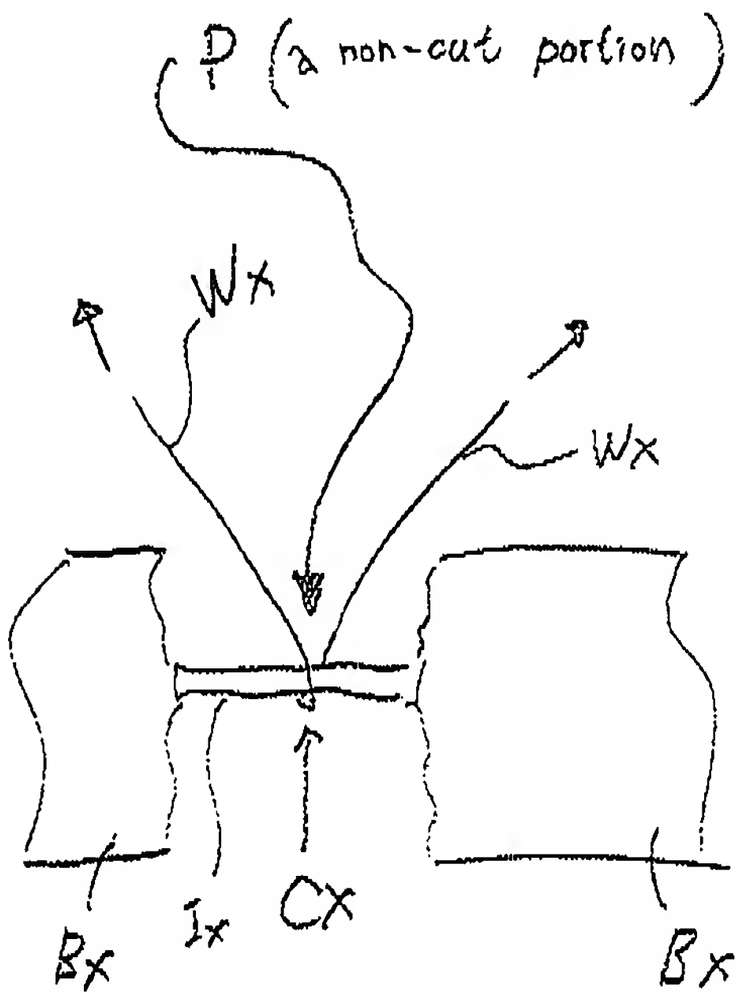
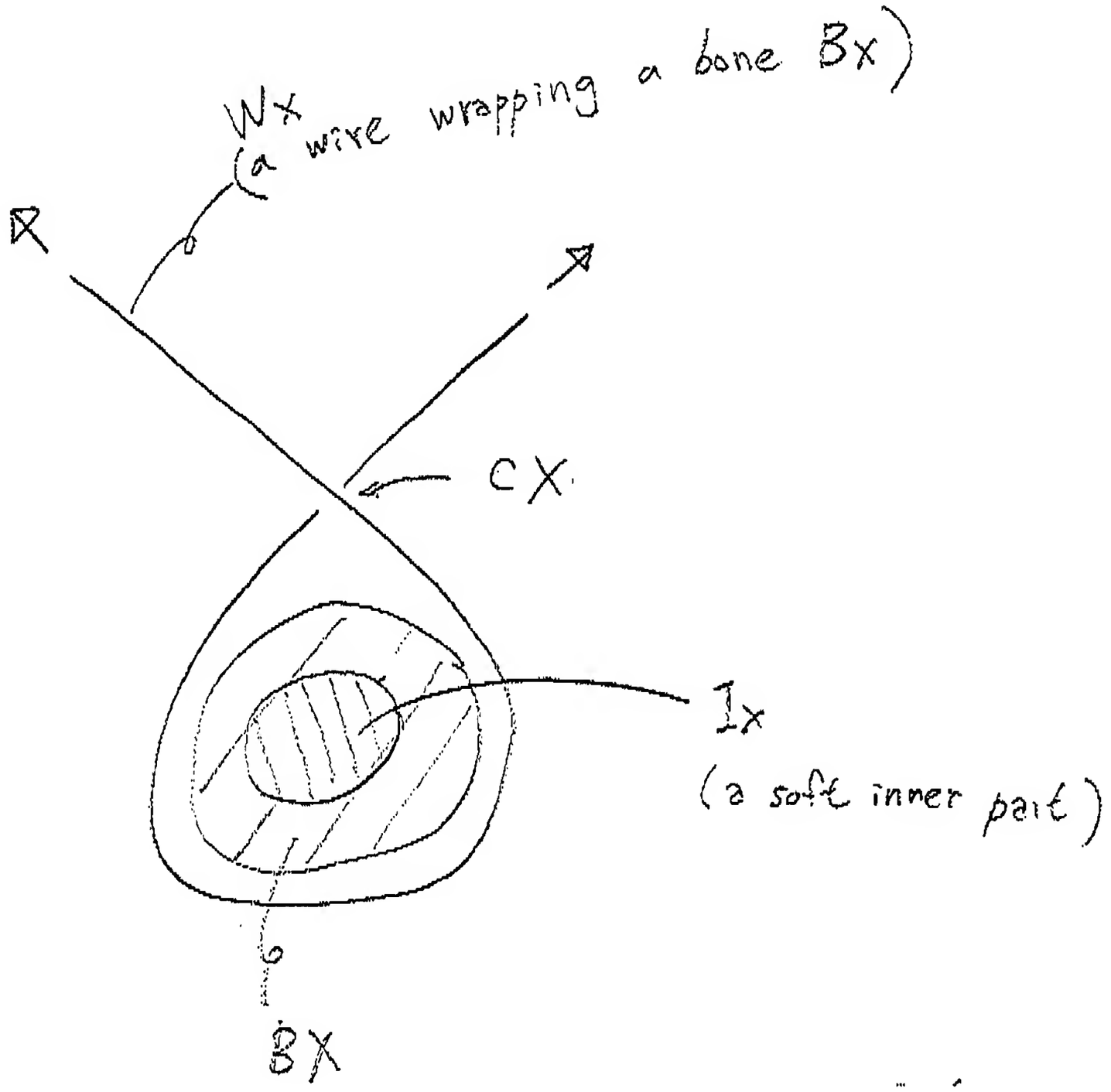



Fig. F-2

In this case, as shown in Fig. E (below), there is a cross portion CX in the wire Wx which is merely wrapping the bone Bx.

Fig. E




As shown in Fig. F-1 (below), while the wire Wx cut the soft inner part Ix, the cross portion CX is formed in the wire Wx. At the final stage of cutting of the bone B, the cross portion CX is positioned in the non-cut portion P as shown in Fig. F-2. This is why the soft inner

part Ix cannot be cut clearly—the cross portion CX is in the soft inner part Ix at the final stage of cutting of the bone Bx.

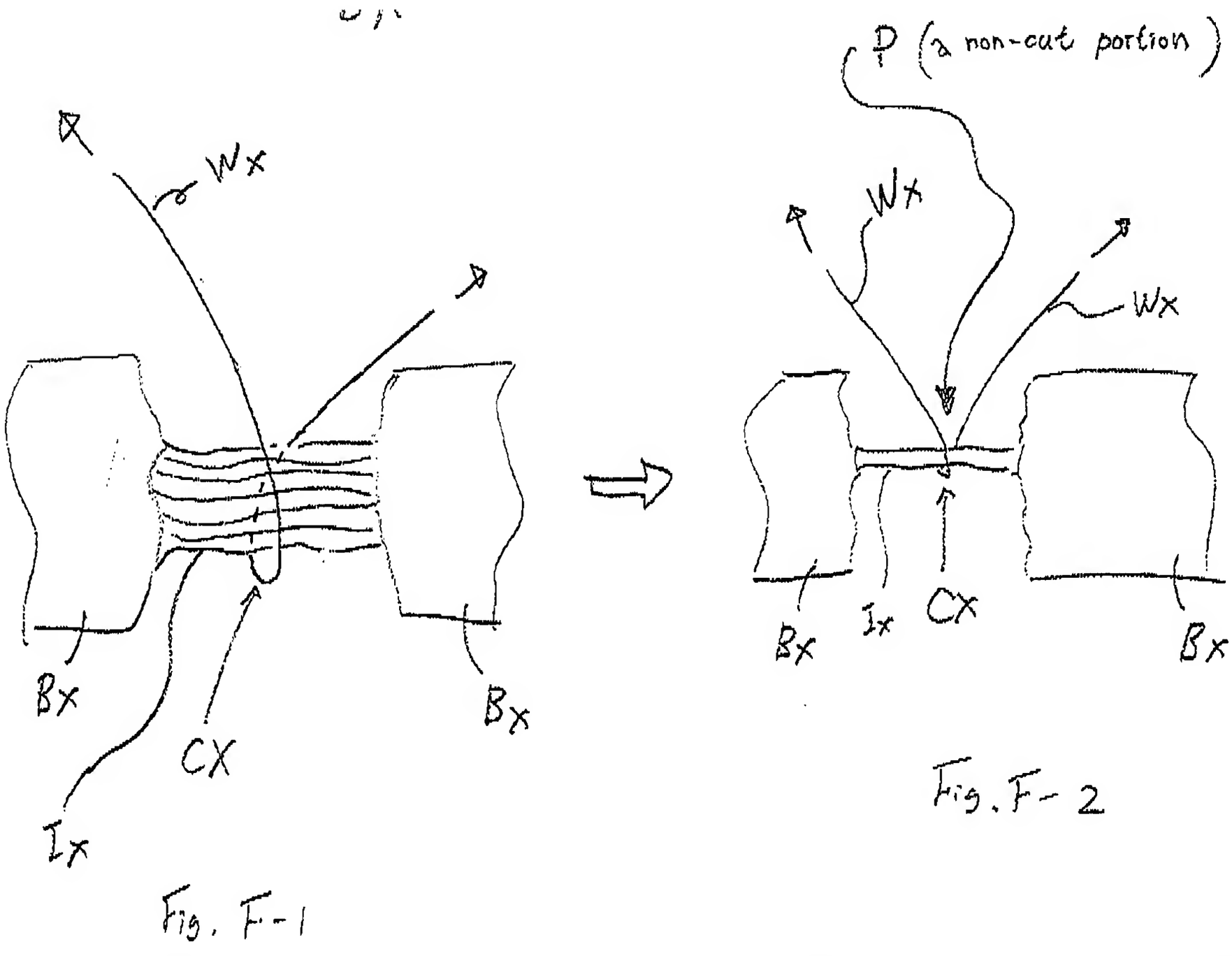


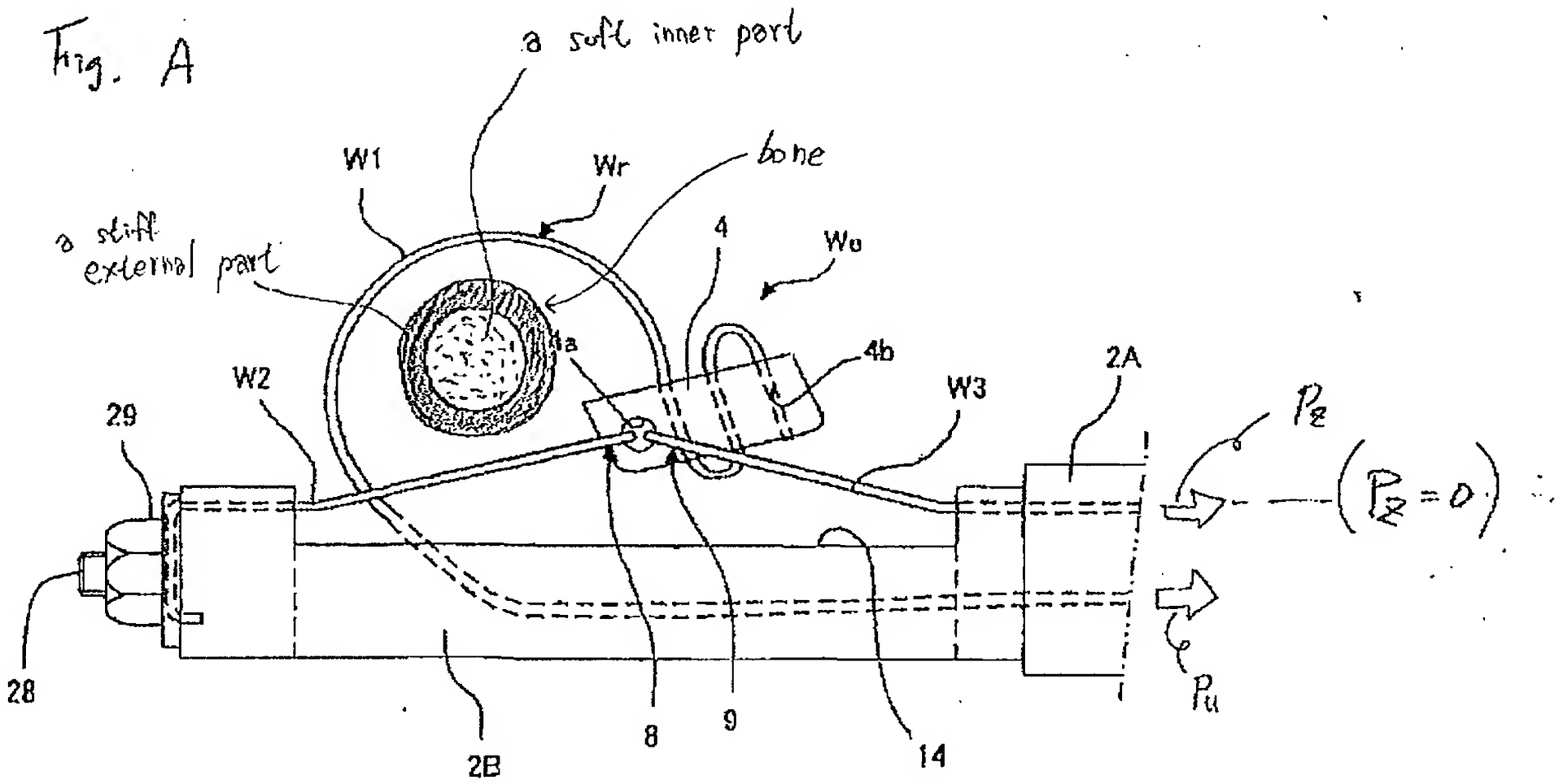

Fig. F-1

Fig. F-2

On the other hand, in the claimed embodiments, by using the cutting wire W1, the first supporting wire W2 and the second supporting wire W3, it is possible to cut a bone having the above-mentioned dual structure in two portions perfectly. In the cutting operation of the claimed bone cutter, as shown in Figs. A to D (below), following steps are carried out.

Step 1. By adjusting the adjust section 25A and the fourth nut 29, the first supporting wire W2 and the second supporting wire W3 hold the position of the fastener 4 moderately tightly.

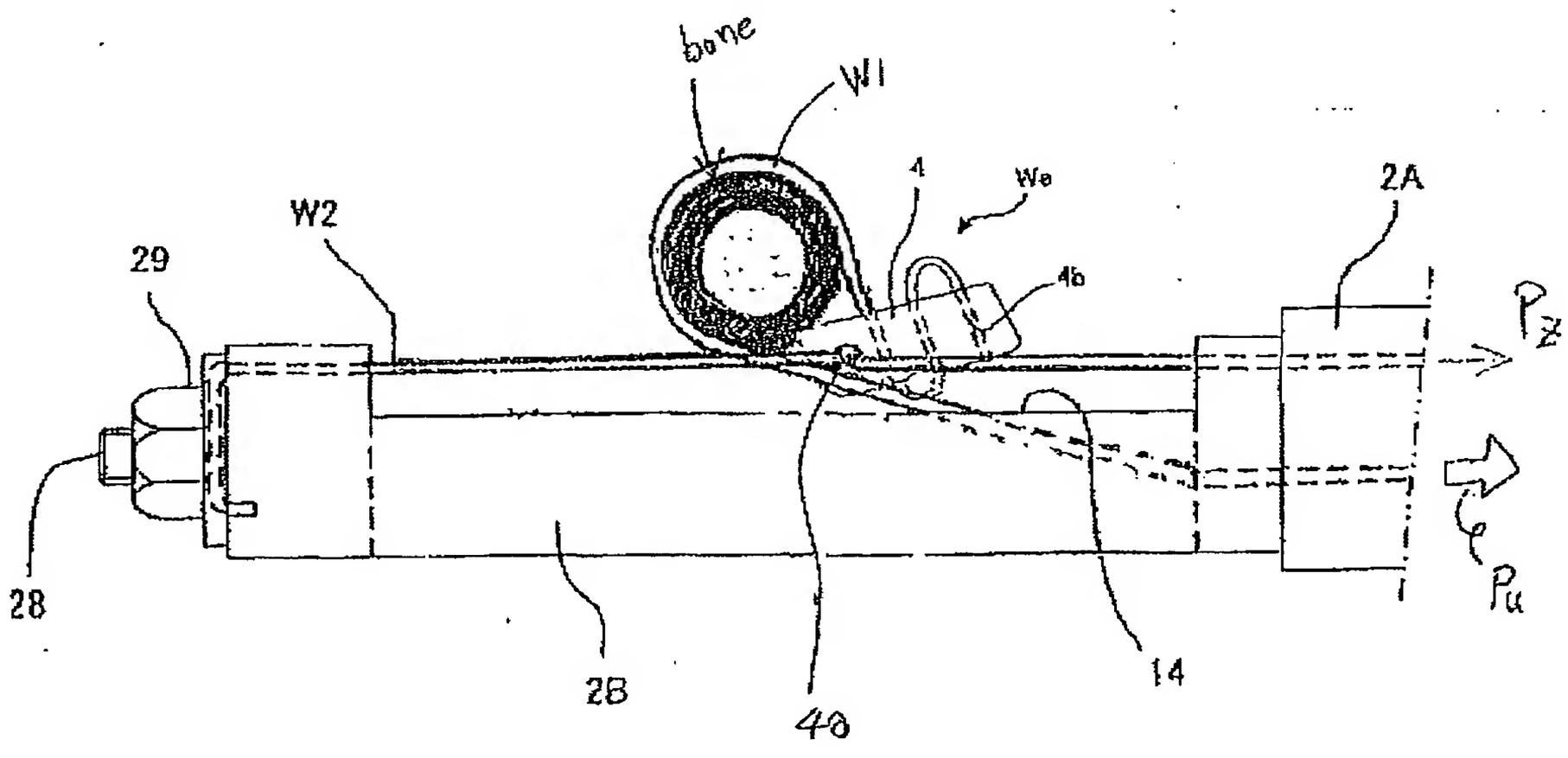
As shown in Fig. A, which corresponds to Fig. 4 of the present application, the cutting wire W1 wraps around a position to be cut in the bone, and the diameter of the circularly curved portion Wr of the cutting wire W1 is determined based on a position and a diameter of the part to be cut. At the stage shown in Fig. A, the tension Pz is not applied. Therefore, the first and second supporting wires W2 and W3 are loosened. In other words, the tension Pz is zero at the stage shown in Fig A.




Step 2. As shown in Fig. B (below), the tension Pz is applied to the first and second supporting wires W2 and W3. Then, the tension Pu is applied to the cutting wire W1. In such a condition, the cutting wire W1 wraps tightly to the circumference of the bone. Also, by the tension Pz being applied to the first and second supporting wires W2 and W3, the hole 4a to which the supporting wires W2 and W3 are fastened is supported so as to hold the position thereof during

the operations shown in Figs. B to C. In the condition shown in Fig. B, the fastener 4 is held in a proper position being defined by the cutting wire W1 and the first and second supporting wires W2 and W3.

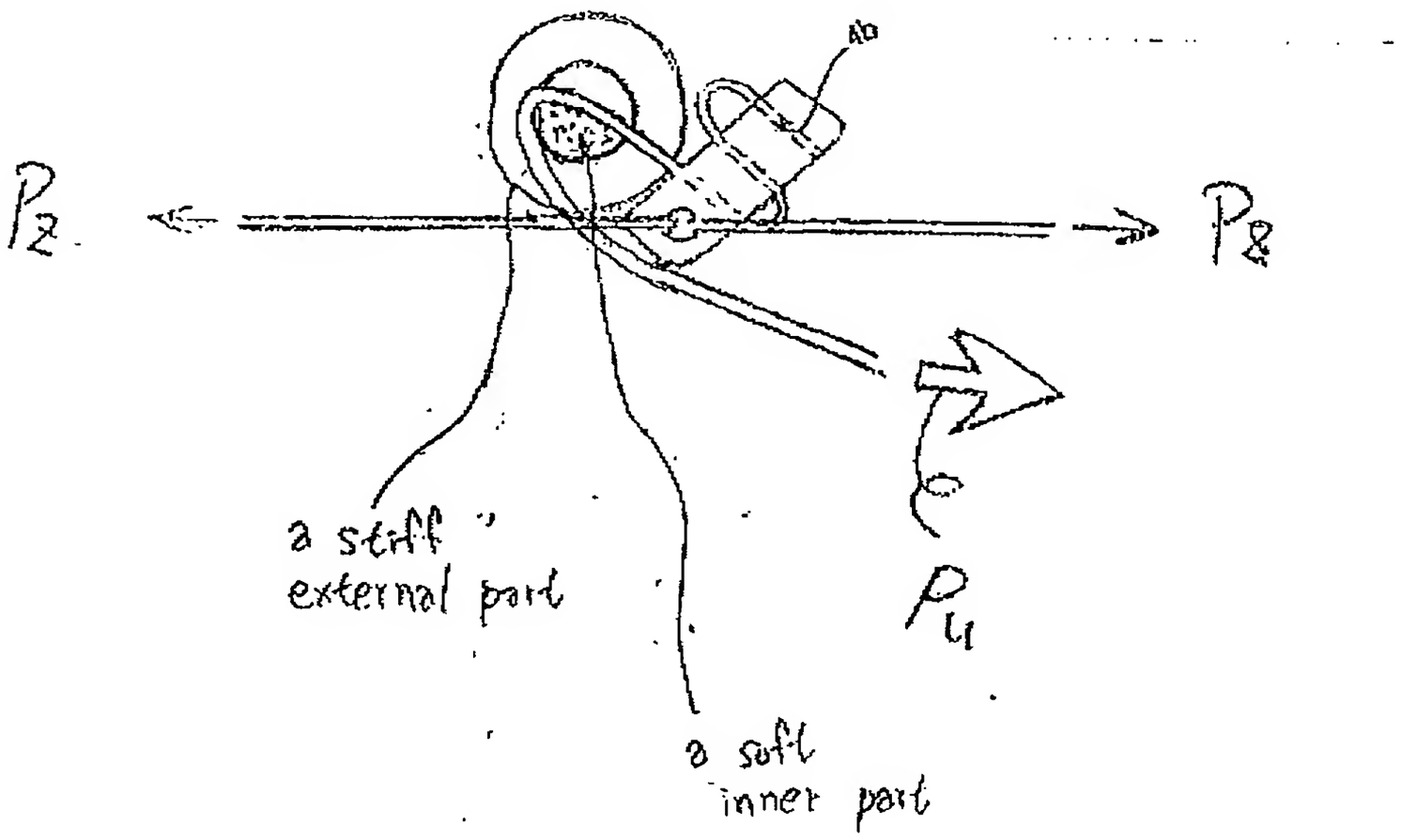
Fig. B




Step 3. At the condition shown in Fig. B, the tension Pu increases. When the tension Pu is a value beyond a threshold level for cracking the stiff external part of the bone to be cut, the position of the stiff external part on which position the cutting wire W1 is wrapped, is cracked and/or cut entirely in the circumference direction of the bone to be cut. In such a situation, the soft inner part of the bone is not cut.

Step 4. After the stiff external part of the bone is cut and/or cracked, the tension Pu increases and the soft inner part of the bone is cut by the cutting wire W1, as shown Fig. C (below). In such the situation, the position of the hole 4a is not moved by the first and second supporting wires W2 and W3. In other words, since the tensions Pz of the supporting wires W2 and W3 are applied to the opposite sides of the hole 4a as shown in Fig. C, the position of the hole 4a does not change during operations of Steps 4 and 5.

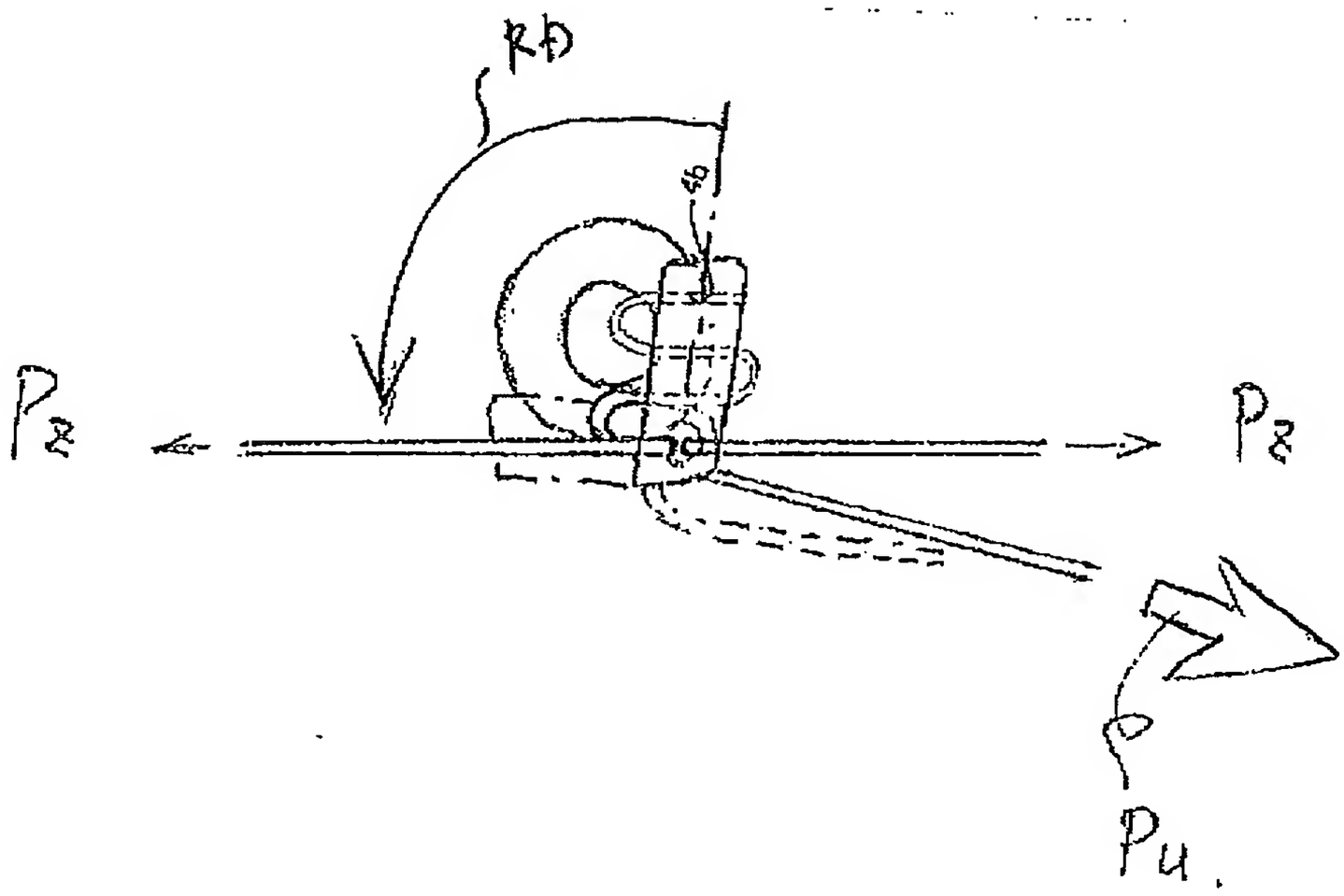
Fig. C




Step 5. At the final stage of cutting of the bone, the cutting wire W1 is further pulled and makes a rotating movement of the fastener 4, as shown in Fig. D (below). The fastener 4 rotates in a

direction being indicated by the arrow RD around the hole 4a. In other words, the hole 4a is a center of the rotation RD. At last, the soft inner part of the bone is cut entirely and clearly by the rotating movement RD of the fastener 4. In other words, the soft inner part of the bone is cut by the cutting wire W1 and the rotating movement RD of the fastener 4 in steps 4 and 5. In step 5, the rotating movement RD of the fastener 4 is generated by applying the tension Pu and holding the position of the hole 4a. Also, the position of the hole 4a is fixed by applying the tension Pz of the first and second supporting wires W2 and W3 to the opposite sides of the hole 4a.

Fig. D



In the present invention, during the operations of steps 1 to 5, a cross portion CX shown in Figures F-1 and F-2 is not generated. Using the claimed bone cutter, a cross section of the bone cut is clear, and also, there is no a non-cut portion P as shown in Fig. F-2 in the soft inner part of the bone. During operation steps 2 and 3, as shown in Fig. B, the first supporting wire W2 and the second supporting wire W3 hold the fastener 4 in the proper position with the cutting wire W1. Therefore, cutting and/or cracking the stiff external part of the bone is accommodated. Also, the first supporting wire W2 and the second supporting wire W3 hold the position of the hole 4a of the fastener 4 during the operations in the above steps 4 and 5 as shown in Figs C and D. Therefore, the fastener 4 rotates and cuts the soft inner part of the bone at the final stage of the cutting.

On the other hand, in the cited art, there are no members analogous to a first supporting wire W2 and a second supporting wire W3. Also, in the cited references, there is no element analogous to the fastener 4 of the claimed bone cutter which rotates and cuts the soft inner part of the bone at the final stage of cutting the bone. Therefore, for at least the above reasons, Applicants respectfully submit that the cited art, either singly or in combination, fails to disclose or suggest the embodiments as claimed. Favorable reconsideration is respectfully requested.

For at least the foregoing reasons, the claimed invention distinguishes over the cited art and defines patentable subject matter. Favorable reconsideration is earnestly solicited.

If the Examiner deems that any further action by applicants would be desirable to place the application in condition for allowance, the Examiner is encouraged to telephone applicants' undersigned attorney.

If this paper is not timely filed, Applicants respectfully petition for an appropriate extension of time. The fees for such an extension or any other fees that may be due with respect to this paper may be charged to Deposit Account No. 50-2866.

Respectfully submitted,

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